



Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE <http://www.niaid.nih.gov/contract/default.htm> FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended. NOTE: The issuance of this solicitation does not commit the government to an award.			
RFP Number: NIH-NIAID-DMID-03-33	Just In Time: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Small Bus. Set-Aside: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 8(a) Set-Aside: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No NAICS Code: 541710 Size Standard: 500 Employees	Level of Effort: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Total Effort: <input type="checkbox"/> N/A <input type="checkbox"/>
TITLE: <div style="text-align: center;">DMID Clinical Trials Management</div>			
Issue Date: October 10, 2002	Due Date: January 7, 2003 Time: 4:00 PM, EST	Technical Proposal Page Limits: <input checked="" type="checkbox"/> Yes (see "How to Prepare and Submit Electronic Proposals") <input type="checkbox"/> No	
ISSUED BY: Jacqueline C. Holden Senior Contracting Officer Contract Management Branch, DEA NIH, NIAID 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, MD 20892-7612		<input checked="" type="checkbox"/> <i>We reserve the right to make awards without discussion.</i>	
		NO. OF AWARDS: <input checked="" type="checkbox"/> Only 1 Award <input type="checkbox"/> Multiple Awards	PERIOD OF PERFORMANCE: 5 years beginning on or about 08/01/2003
Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)			
The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.			
POINT OF CONTACT -- Joshua LaVine/Michelle Scala --COLLECT CALLS WILL NOT BE ACCEPTED--			
Telephone: TTY# 1-800-735-2258 ask for 301-496-2509 or Main 301-496-0612 or 301-496-0189	Fax 301-402-0972		E-Mail JLaVine@niaid.nih.gov and ms35n@nih.gov

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Background

DMID Clinical Trial Management
DMID-03-33

INTRODUCTION

The National Institute of Allergy and Infectious Diseases (NIAID), NIH, research strives to understand, treat, and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents. This includes basic biomedical research, such as studies of microbial physiology and antigenic structure; applied research, including the development of diagnostic tests; and clinical trials to evaluate experimental drugs and vaccines.

The evaluation of experimental vaccines and therapeutic agents has historically been a major focus of the research supported by DMID. DMID has an extensive network of clinical contracts and grants to address programmatic priorities in vaccine and therapeutic evaluation for all non-HIV infectious diseases, including those pathogens associated with emerging diseases and biodefense. The DMID clinical research program supports a large and growing number of domestic and international multi-center trials and single-center clinical studies (Phase I-IV), which are conducted among all populations, including infants and children, adolescents, adults and the elderly. Currently, DMID is either the financial and/or Investigational New Drug (IND) sponsor of over 100 IND applications or Master Files that consist of approximately 130 on-going clinical trials. It is anticipated that 30 new clinical trials/studies will be initiated each year, and this number is likely to increase in the future.

As a result of the rising number of clinical trials associated with biodefense and with an increased focus on rigorous clinical trial conduct, DMID has a need to bolster its current clinical trials management capacity. Thus, with this RFP, DMID is seeking a comprehensive clinical research support contract to provide a wide range of clinical trial management services for a variety of clinical research efforts. Specific tasks performed will vary by clinical trial and/or clinical site, and will be dependent on the trial's protocol, standard operating procedures, and the roles/duties assigned to the Contractor by the DMID Project Officer. Trials will be funded by the DMID and are usually under DMID IND sponsorship, although occasionally a pharmaceutical company partner may serve as IND sponsor. Selected tasks associated with these trials may be provided by the partner or other DMID contractors and grantees therefore the contractor must be willing to collaborate with these entities and provide an interface for communication and information flow.

The overall objective of this contract is to provide clinical trial management to DMID's clinical research program. The Contractor will assist DMID in the management of its clinical research program by providing the following clinical trial support:

- A. Clinical site assessment;
- B. Clinical site preparation and clinical trial operational assistance, including the establishment of appropriate internal Quality Control/Quality Assurance (QC/QA) procedures and systems;
- C. External Quality Assurance monitoring;
- D. Pharmacovigilance/Safety Monitoring;
- E. General logistical support and administrative coordination for DMID's clinical research program; and
- F. Implementation and maintenance of information management systems.

This contract will place particular emphasis on the QC and QA systems and procedures. The contractor will be responsible for establishing and/or enhancing **internal** QC/QA programs for specified DMID clinical sites. This internal QC/QA program, including an internal clinical monitoring plan, and an internal data quality assurance system, shall provide the framework for all quality control and assurance activities related to the conduct of the protocol at the clinical site.

In addition, the contractor, when requested by the DMID Project Officer, will also be responsible for providing an **external** Quality Assurance program tasked with performing independent clinical monitoring and oversight of trial-related activities to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practices (GCP) and the applicable regulatory requirement(s).

In order to maintain unbiased and objective evaluations of clinical trial conduct, the external QA program and staff responsible for monitoring a clinical site must be independent and separate from the clinical trial site's internal QC/QA program and staff.

**Statement of Work
DMID Clinical Trial Management
RFP DMID-03-33**

STATEMENT OF WORK

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the work set forth below. All activities of this Statement of Work will require prior approval by the DMID Project Officer, unless otherwise noted.

A. CLINICAL SITE ASSESSMENT

Assess sites participating in DMID clinical trials.

1. Survey DMID-identified clinical research sites for capabilities in the initiation and conduct of DMID-supported clinical trials.
2. Develop and distribute clinical site feasibility assessment tools to assess site capability and readiness for DMID clinical trials. This assessment shall include adequacy of all site facilities to be used for clinical trials, including the pharmacy, clinical units, clinical laboratories, other laboratories and storage area for records.
3. Conduct site feasibility assessment visits for the purpose of evaluating clinical sites facilities and staff. Analyze and report results of site assessments and make recommendations to DMID regarding clinical site suitability.

B. CLINICAL SITE PREPARATION AND CLINICAL TRIAL OPERATIONAL ASSISTANCE

Provide comprehensive clinical trial management and support services to DMID clinical trial sites during all phases of trial conduct (i.e., trial preparation and initiation through trial completion and close-out). Typical activities are wide-ranging, site and protocol dependent and shall include, but are not limited to:

1. **Assist sites in preparatory activities in advance of the conduct of clinical trials.**

These activities shall include but are not limited to:

a. Review of Operations

- 1) Conduct comprehensive site operational assessment visits. Assessment visits shall be performed by qualified personnel and shall include the inspection of laboratory, pharmacy, clinical, data and regulatory operations at trial sites. Site operational assessment visits may continue throughout the duration of the trial.
- 2) Generate site visit reports and provide to the DMID Project Officer and site investigators within ten (10) working days of each visit. Site visit reports shall include an executive summary of findings, detailed findings and a tabulated listing of corrective actions.
- 3) Work with site personnel to resolve all noted deficiencies. Mechanisms to electronically track resolutions will be required, including entering pertinent site assessment visit data into a monitoring database. (See paragraph C.5. for more information.)

- b. Design, prepare and distribute DMID-approved site preparation aids (e.g., listing of essential documents, regulatory binders with suggested table of contents, a checklist of essential site qualifications, sample Standard Operating Procedures) and other tools to facilitate site organization.

- c. Ensure that all legally binding site documents (e.g., letters of agreements, clinical trial agreements, confidentiality agreements) are in place prior to trial initiation.
- d. In coordination with the DMID Project Officer and/or IND sponsor, document the responsibilities and obligations of the IND sponsor and the Contractor, acting as the Contract Research Organization (CRO).

2. **Study Documents and Materials Generation/Distribution**

Collaborate with and respond to investigators, DMID staff and/or FDA or other regulatory bodies in devising sound and mutually acceptable protocol-related and adjunctive study documents. Documents/materials shall include:

a. **Protocol Documents/Materials**

- 1) Assist DMID clinical investigators in the design, development, writing and review, including the collection and synthesizing of review comments, of protocols and protocol amendments, risk information, Investigator Brochure updates, study manuals of procedures, source documentation guidelines, study specific procedures, case report forms, and informed consent forms. Contributions may include medical writing, scientific/medical review, data management review of protocols and case report forms, regulatory review of protocol and informed consents.
- 2) Develop and use DMID-approved standardized protocol and associated document templates, when appropriate.

b. **Adjunctive Documents/Materials**

- 1) Develop and provide to sites and appropriate DMID staff original and updated SOPs, communication plans, protocol responsibility grids, trial timelines/milestones, press and public information materials, and various study reports for a range of scientific and lay audiences.
- 2) Establish and communicate to DMID and sites trial-related timelines for deliverables.

3. **Provide technical assistance, at the request of the Project Officer, in the assembly and review of documentations for Investigational New Drug Application (IND) submissions to the FDA, as described in 21 Code of Federal Regulations (CFR) 312.23.**

4. **Provide general management and operational support to the Investigators and study team.** At a minimum, areas of support include the following:

- a. Answering protocol-specific or general questions, or forwarding the question to the appropriate resource (e.g., regulatory authorities);
- b. Interfacing with DMID contractors, grantees as well as pharmaceutical partners, if any;
- c. Assisting sites in protocol-specific preparedness activities; and
- d. Assisting sites to ensure that clinical trials are conducted in accordance with ICH/GCP (International Conference on Harmonization/Good Clinical Practices) guidelines.

5. **Assist DMID clinical sites in the Establishment and/or Enhancement of Internal Quality Control/Quality Assurance (QC/QA) programs**

The Contractor shall be responsible for assisting designated sites in the development, implementation and on-going assessment of **internal** QC/QA programs. The QC/QA program, including the structure and defined responsibilities of clinical trial investigators, shall provide the framework for all quality control and assurance activities related to the conduct of the protocol. At a minimum, specific activities shall include:

- a. Assisting sites in preparing Standard Operating Procedures (SOPs) for quality control and quality assurance (QC/QA) activities.
- b. Providing appropriately qualified staff to assist sites in the review and resolution, with associated documentation, to issues identified in site assessment reports and/or in External QA site monitoring reports.
- c. Dialoguing and working with sites to correct deficiencies and, if necessary, providing local (on-site) support to correct problems, including conducting follow-up site assessment visits and providing training. Reporting progress of remedial action to DMID as directed. Mechanisms to electronically track resolutions will be required.
- d. Assisting sites in the establishment of internal data quality assurance systems to ensure that study data are complete and accurate, and that the sites are adhering to GCP standards, protocol specification, regulatory requirements and governing policies.
- e. Assisting sites in the development and implementation of internal clinical monitoring plans.
- f. Developing methods of quality control, including quality control tools (e.g., checklists, pareto charts, flowcharts, cause and effect diagrams, histograms, scatter diagrams and control charts), and monitoring study activities to ensure standardization and high quality of collected data in all areas.
- g. Developing and maintaining record keeping and filing procedures of all relevant material, logging in all decisions made that affect study design, conduct, or analysis.
- h. Reporting verification rates, discrepancy rates, and error rates for data collection, preparation and computer entry.

6. Training and Training-Related Activities

- a. Provide clinical research-related training to study site personnel (including investigators) and DMID staff as required to facilitate sound protocol conduct and clinical trial management. Training topics may include GCP training, MedDRA (the Medical Dictionary for Regulatory Activities) training, international and federal regulations and requirements training (e.g. quality assurance and quality control, informed consent, IRB procedures and safety reporting), protocol specific training, principles of data management training, handling of study product training (e.g., storage, recordkeeping, dispensing), laboratory procedures for clinical research training, and other training as required.
- b. Perform needs assessments to determine the training requirements of clinical study personnel, and the most suitable and efficient mode of providing training (e.g., on site, via telephone, via teleconferencing, via written materials, via websites).
- c. Develop, distribute and update training materials as necessary. Training materials and all updates shall be presented to the DMID Project Officer for approval prior to distribution. Training materials may be required in multiple languages and formats (e.g., hard copy, CD-ROM and website).
- d. Develop monthly schedules for the delivery of training (including the mode of delivery) and provide to the DMID Project Officer for approval prior to performance.
- e. Establish and implement mechanisms for the evaluation of training activities. Modify training courses, techniques and/or materials accordingly to improve training activities based on the results of evaluation processes.
- f. Create list-serves for the purpose of providing clinical trial staff with information regarding upcoming policy or procedure changes and training opportunities.

- g. Establish a central training documentation mechanism to record and report status of training activities for clinical investigators and staff. This training component includes, but is not limited to, the identification of training requirements and associated frequency, completed training, and expiration of training.
- h. Develop and maintain website(s), at the request of the Project Officer, that allow clinical trial staff to receive on-line training, access archives of previous training, order training materials, and provide other relevant training information as identified. (See paragraph F., below, for more information on website structure and design.)

7. Laboratory procedures for clinical research

- a. Provide general laboratory assistance to sites to develop standard procedures for the appropriate collection, labeling, shipping and storage of laboratory specimens.
- b. Provide qualified personnel to assess the adequacy of laboratory quality control procedures and assist clinical site laboratories in the development of SOPs and quality assurance procedures.
- c. Develop laboratory specimen tracking systems as requested by the Project Officer.
- d. Provide central laboratory support for the conduct of routine safety inspections for specified trials, and provide quality assurance and project management of such an effort.

8. Shipping

Provide specialized operational support when necessary for specimen shipping. Activities shall include but are not limited to:

- a. Procuring shipping containers and commercial shippers for the transfer and shipping of samples.
- b. Working with specified DMID personnel on shipping processes and customs interface.
- c. Advising DMID as to shipping timelines and problems in particular areas with an emphasis on clinical trial related materials from/to international settings.
- d. Monitoring International Air Transportation Association (IATA) certification and compliance for clinical sites.
- e. Providing guidance to investigators on shipping procedures when necessary.

9. Product/Agent distribution

In the event that the DMID does not utilize an existing distribution agreement, the Contractor shall provide test articles (e.g., study drug) to both U.S. and international sites. Activities shall include but are not limited to:

- a. Procuring, storing, managing and distributing test articles to DMID-designated clinical sites.
- b. Conducting distribution in accordance with all applicable shipping (import, export, destruction) guidance policies and regulations and with the appropriate quality control mechanisms in place to assure appropriate handling and storage conditions, and drug accountability.
- c. Verifying, prior to product/agent distribution, that each site receiving shipments meet DMID pharmacy requirements.
- d. Producing and submitting to the DMID Project Officer for approval a manual with SOPs to demonstrate appropriate compliance and sound management of products.

C. EXTERNAL QUALITY ASSURANCE (QA) MONITORING

Support the DMID in providing external QA monitoring when needed. The Contractor is responsible for assuring that all monitors are appropriately trained and have sufficient scientific and clinical background, knowledge, training and protocol-specific materials to effectively perform the required tasks. In addition, the Contractor shall be responsible for ensuring that the monitors adhere to the SOPs and that all site visits are conducted uniformly and consistently between monitors and across sites. Continuity of monitors for given projects is essential. QA monitors must be able to travel to DMID-designated sites within two (2) weeks notice. Depending on trial complexity, the capability to provide additional monitors for specific projects may be required. The Project Officer, based on safety issues, experience of the site, type of trial and other factors, will determine the number and length of site visits.

As a minimum, specific activities shall include:

1. **Arranging and conducting external clinical on-site monitoring and Quality Assurance/GCP (QA/GCP) visits** to selected sites, as assigned by the DMID Project Officer, to determine compliance with: U.S. Federal requirements, specifically those found in 21 CFR 50, 56, 312.50 and 312.60; ICH or other applicable regulations for international sites; and DMID standards and procedures for the conduct of clinical trials. The intent of this QA process is to ensure that study data are complete and accurate, and to ensure adherence to GCP standards, protocol specification, regulatory requirements and governing policies. Specific activities shall include but are not limited to:
 - a. Assessing the site's internal quality assurance and quality control methods and procedures governing the DMID clinical trials;
 - b. Adherence to GCP guidelines as per U.S. or ICH, and local regulations;
 - c. Assessing the procedures for requesting and obtaining laboratory and diagnostic reports and other clinical records;
 - d. Evaluating the proper storage of confidential information, the proper storage and accountability of test articles and specimens, and the completeness of regulatory files;
 - e. Evaluating the space and facilities for conducting clinical trials;
 - f. Observing clinical operations such as the consent process; and
 - g. Reviewing case report forms and comparing these to source documentation for completeness and accuracy.
2. **Types and frequency of on-site monitoring visits** will vary by trial (e.g., protocol qualification, protocol initiation, protocol interim, and protocol close-out visits).

At a minimum, the contractor shall:

- a. Conduct site monitoring visits of all DMID clinical sites performing clinical studies at least annually and more frequently when requested by the Project Officer.
- b. Perform special audits if there are significant irregularities found through quality control procedures (e.g., data discrepancies, protocol violations, human subjects issues, or other problems) or when allegations of scientific misconduct are made. Special audit visits shall be scheduled at the request of the DMID Project Officer. Other Federal agencies or offices may be invited to participate in a special audit at the discretion of the Project Officer.
- c. In cases where trials are monitored by a third-party, including other DMID Contractors, the Contractor may be expected to provide Quality Assurance/GCP visits to ensure the appropriateness and quality of existing monitoring procedures.

3. Preparation for and Scheduling of Monitoring Visits

- a. Generate an initial monitoring plan for each trial in conjunction with DMID staff and make recommendations as to key variables and the percentage of records to be monitored, prior to the assigned visit. Typically, DMID does not conduct 100% monitoring. Monitoring plans shall be subject to DMID Project Officer review and approval.
- b. Notify clinical sites/organizations in advance of the scheduled site visit date. The DMID Project Officer shall be informed of planned visit dates. On occasion, the DMID Project Officer or appointed staff may attend initiation visits and/or other interim monitoring visits.
- c. Provide clinical trial sites/organizations with a list of protocols and subjects to be audited at least two (2) weeks prior to the scheduled site visit date.
- d. When possible, it is desirable to consolidate the scheduling of visits so that an institution conducting several clinical studies is not required to undergo multiple visits during a single year. For example, an institution conducting four studies would be visited once a year and all four studies would be evaluated during that visit. In this way, travel costs can be reduced. The Contractor shall develop the procedures and logistics for conducting such a consolidated single visit.

4. Monitoring Visit Reporting

- a. Prepare and submit to the DMID Project Officer for review and approval site monitoring reports and draft letters to the Principal Investigators at the visited sites, no later than two (2) weeks following the completion of each site visit. At a minimum reports shall include the following items:
 - 1) Protocol numbers, abbreviated protocol title and subject ID numbers of all cases reviewed;
 - 2) A listing by protocol of all protocol-specific deficiencies revealed by the site monitoring visit and, when appropriate, recommendations for corrective actions to be taken to resolve any problems and deficiencies noted;
 - 3) Identification of any site-specific operational issues or problems.
 - 4) A description and assessment of any problems identified from previous visits that have not been corrected, the reasons why such problems have not been corrected, and recommendations for corrective actions when appropriate; and
 - 5) The names of the clinical site staff with whom all problems and deficiencies were discussed, a description of the site's plan for their correction, the site personnel responsible for implementing corrective actions, and a brief description of improvements noted in site performance.
- b. If serious deficiencies or concerns regarding site performance are noted, the monitor shall notify the Project Officer by telephone within 24 hours from the time of discovery of the serious deficiency.
- c. In consultation with the study investigators and DMID, the Contractor shall formulate actions to be taken to address the issues or problems identified and track them until they are resolved.

5. Develop and implement an electronic (web-based) system for monitoring site visits to:

- a. Notify clinical trial site investigators of scheduled visits;
- b. Send audit results to clinical site investigators and appropriate DMID staff;
- c. Notify site investigators of required follow-up, if any; and
- d. Tracking follow-up information.

6. **Enter pertinent site monitoring and site assessment report information** (e.g., monitor action items, problems/deficiencies, recommended mode to resolve problems/deficiencies and status of resolution) into the monitoring database. (See paragraph F., below, for more information on database structure and design.) At a minimum, the Contractor shall:
 - a. Maintain and update this database as necessary throughout the conduct of a clinical trial.
 - b. In cases where monitoring is provided by a third party or other DMID contractors, the Contractor shall work with these parties to secure QA monitoring reports and import or export the reports into the DMID designated database using commercial software.
7. Receive and participate in review of site monitoring reports prepared for studies where another NIAID contractor or pharmaceutical partner is conducting site monitoring.
8. Develop and maintain a manual of Standard Operating Procedures (SOPs) for the conduct of all types of site monitoring visits (e.g., initiation visits, interim audit visits, close-out audit visits and special assignment visits).

D. PHARMACOVIGILANCE/SAFETY MONITORING

Design, develop, implement and maintain a global Adverse Event/Serious Adverse Event (AE/SAE) reporting system that will constitute DMID's Pharmacovigilance Program. At a minimum, specific activities shall include:

1. Coding all reported adverse event terms into a standardized international terminology, MedDRA (the Medical Dictionary for Regulatory Activities).
2. Abstracting adverse event information into a centralized database. This will involve interfacing with clinical investigators and DMID's Data Coordinating Center contractor to obtain adverse event report information. (See paragraph F. for database information.)
3. Providing for scientific and medical review of AE/SAE, assessment of "reportability" status and compliance, and generating draft and final safety reports.
4. Providing SOPs for adverse event review, including AE/SAE flow process with charts for site use and site clarity.
5. Providing 24 hours/7 days per week medical personnel coverage, whose qualifications are acceptable to DMID, for consultation to clinical sites and/or DMID medical staff.
6. Providing weekly, monitoring and ad hoc safety listings, dependent upon the request of the protocol group.
7. Safety monitoring may at times be provided by DMID, other DMID grantees or contractors or third-party external monitors, therefore an interface/communication plan and guidelines shall be defined prior to study initiation as it relates to safety responsibilities.
8. Developing, implementing and maintaining quality control/assurance procedures and ongoing training of clinical site staff to ensure consistency, completeness and accuracy of SAE reporting.
9. Transmitting SAE reports to DMID and DMID-designated entities; e.g., Data Safety and Monitoring Boards (DSMBs), investigators.
10. Ensuring compliance with regulatory requirements and activities including safety surveillance, safety strategy, representation and communication with regulatory authorities.
11. Providing support to the DMID Medical Monitors in managing adverse event reports.

12. Developing and implementing a transition plan from the current system (paper system) to the new system of centralized data collection. The current system shall be maintained until the new process is fully implemented.

E. GENERAL, LOGISTICAL AND ADMINISTRATIVE SERVICES TO ASSIST THE DMID/NIAID IN THE MANAGEMENT OF ITS CLINICAL RESEARCH PROGRAM

Provide programmatic and protocol-specific support that shall include but not be limited to:

1. **Meeting Support** – This includes investigator meetings, protocol meetings, trial start-up meetings, DSMB meetings, and scientific workshops. Provide comprehensive meeting support to include meeting arrangements, agendas, travel, graphics and video support, comprehensive logistics and materials preparation and distribution. Provide meeting summary reports.
2. **Communications** - Establish reliable electronic communication links with DMID and with clinical sites, which permits sending mail and sharing word processor and data files. Websites for protocol and program communication(s) shall be implemented with appropriate secured access. Contractor shall maintain compatibility with standard software. Initiate conference calls for projects and protocols on an ongoing basis, as well as attend these calls and prepare/distribute minutes.
3. **Study material distribution** – Provide, develop, review, edit and distribute DMID-approved trial-specific and overall program support materials (e.g., recruitment materials, manuals of procedures, protocols, thermometers). Make recommendations to DMID and the clinical investigators as to the best medium for study material distribution. Coordinate with DMID staff and clinical investigators on the preparation, printing and distribution of volunteer education materials, recruitment and retention materials to include web-based mechanisms, radio and television commercials and printed media.
4. **ClinicalTrials.gov** – Initiate and maintain a link to www.clinicaltrials.gov, and provide assistance to study investigators in the preparation of protocol summaries and all necessary updates to the ClinicalTrials.gov website. Provide on-going reviews of program submitted information within the website to insure that clinical trial information is current and accurate. All information must be approved by the DMID Project Officer. In addition, establish and manage a toll-free telephone number (e.g., “Call Center”) and a website to provide information to the public who may be interested in obtaining further details about DMID-sponsored trials listed on the ClinicalTrials.gov site.
5. **Study file management and archiving services** -- To include the management of central files for designated studies and the archiving and cataloguing of administrative and research records.
6. **Routine or specialized immunogenicity tests** -- At the request of the Project Officer, the contractor will identify and subcontract with specialized laboratory facilities to provide routine or specialized immunogenicity tests (e.g., ELISA, ELISPOT, Antibody neutralization) and/or therapeutic-related (e.g., viral load, CD4) assessments.

F. INFORMATION MANAGEMENT ACTIVITIES

1. Databases

Develop (using commercial software) and maintain centralized databases necessary to support the clinical trial management activities outlined in the Statement of Work. All databases are subject to DMID Project Officer approval prior to development. Databases are to meet the informational needs defined by DMID, be developed using commercial off-the-shelf software and be compatible with NIAID standards and with other existing and planned DMID applications. In addition, the system shall be consistent with Code of Federal Regulations (CFR), NIAID informatics standards, relevant industry standards, and applicable Health Insurance Portability Protection Act (HIPPA) standards for data integrity, confidentiality, and security. The Contractor shall assure that clinical trials data are entered into the database with identifying numbers only. Patient names and other identifiable information shall not be used. The Contractor shall be responsible for assessing the legacy data and transferring relevant information to the new database. The legacy data will be supplied by DMID.

Databases to be developed include, but are not limited to:

- a. A database to track monitoring action items and deficiencies noted in site assessment and monitoring reports, and resolution of these deficiencies. The database shall be designed with the ability to note trends, flag unresolved problems and generate monthly reports of monitoring deficiencies (by site and by protocol) with recommendations to the DMID Project Officer.
- b. A database for Adverse Event/Serious Adverse Event (AE/SAE) reporting. (See paragraph D.2. for more information.)
- c. A database to track clinical trial metrics.
- d. A database to track training.

2. Websites

Develop (using commercial software) and maintain websites necessary to support the clinical trial management activities outlined in the Statement of Work. All websites are subject to DMID Project Officer approval prior to development.

3. Special Reports

Prepare study status and site-specific performance reports including, but not limited to, accrual and retention of study participants, timeliness of data submission, and adherence to protocol specifications.

4. Electronic filing system

Develop and maintain an electronic filing system containing final clinical protocols and consent forms.

G. CONTRACT TRANSITION

1. Develop a written transition plan, subject to Project Officer approval, to ensure the orderly transfer of all or part of this project to a designated Contractor, if other than the incumbent, during a period prior to completion of this contract, to be specified by the Government.
2. For the clinical monitoring portion, actively instruct employees of the new Contractor on all site monitoring procedures and standards in current use, as well as all pertinent information regarding the sites, including but not limited to: organization; staffing; working relationships and communication mechanisms; internal quality assurance and quality control program; problems and deficiencies identified with respect to clinical site operations and remedial actions taken or recommended; and overall site performance.
3. For the investigational agent distribution portion, safely and efficiently move the investigational agents and records to the new location(s) designated by DMID.
4. Effect a smooth transfer of all databases, data/information and other files and materials required under the contract to the Government.

[END OF STATEMENT OF WORK]

Reporting Requirements and Other Deliverables
Clinical Trials Management
RFP DMID-03-33

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1., DELIVERIES of this contract:

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These shall be brief and factual and prepared in accordance with the following format:

A. Technical Progress Reports

In addition to those reports required by other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below. All reports shall be submitted as hard copies and in electronic form, as computer files, in Microsoft Word™ version 9.0 for Windows and Microsoft Excel™ version 9.0 for Windows, with formats readable with an IBM-type personal computer. Files shall be sent by E-mail, or on 3.5" discs by U.S. mail or courier service. All reports shall be archived on 3.5" discs or other appropriate media for surrender to the Government at the completion of the contract.

1. Semi-Annual Technical Progress Reports - By the fifteenth calendar day of the month following the end of each six month period, the Contractor shall submit four (4) copies of a semi-annual Technical Progress Report, comprised of three (3) copies to the Project Officer and one (1) copy to the Contracting Officer. As a minimum, such reports shall include the following specific information:
 - a. A cover page that lists the contract number and title, the period of performance being reported, the Contractor's name and address, the author(s), and the date of submission;
 - b. SECTION I - An introduction covering the purpose and scope of the contract effort;
 - c. SECTION II - A description of overall progress plus a separate description for each task or other logical segment of work on which effort was expended during the report period;
 - d. SECTION III - Description of any technical or performance problems encountered and corrective actions planned or taken. An explanation of any differences between planned and actual progress will be included; and
 - e. An anticipated work plan for the next six months.

A semi-annual report will not be required for the period when an annual or final report is due.

2. Annual Reports - By the fifteenth calendar day following the anniversary date of the contract, the Contractor shall submit four (4) copies of an annual Technical Progress Report, comprised of three (3) copies to the Project Officer and one (1) copy to the Contracting Officer. At minimum, these reports are to include the information prescribed above (Item 1.) and a summation of the work performed and results obtained for the entire period covered. An annual report will not be required when the final report is due.
3. Transition Plan - During a period prior to the contract completion date, to be specified by the Project Officer, the Contractor shall develop a written transition plan, subject to Project Officer approval, to ensure the orderly transfer of all or part of this project to a designated Contractor and/or the Government. The Contractor shall provide (4) four copies of the Transition Plan, comprised of three (3) copies to the Project Officer and one (1) copy to the Contracting Officer.
4. Final Report - By the completion date of the contract, the Contractor shall submit four (4) copies of a comprehensive Final Report, comprised of three (3) copies to the Project Officer and one (1) copy to the Contracting Officer. As a minimum, this report shall include the information prescribed above (Item 1.) and a summation of the work performed and results obtained for the entire contract period of performance. This report shall be sufficient in detail to describe the results achieved.

5. Other Deliverables (to Project Officer only)

The second table, below, identifies the other deliverables that are identified throughout the Statement of Work, Article C.2, that are to be submitted only to the Project Officer during the entire contract period of performance.

6. Distribution

It remains the responsibility of the Contractor to assure receipt by the Government official listed below of all deliverables by the established due dates. If the Contractor is unable to deliver the items specified hereunder within the period of performance, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore.

Copies of the technical reports shall be submitted to the Project Officer and the Contracting Officer as follows:

Type of Deliverable	No. of Copies	Addressee/Distribution	Due Dates
Semi-Annual Report	3 1 (Original)	Project Officer, Contracting Officer	Within 15 calendar days after each 6 month period from the time of contract award.
Annual Report	3 1 (Original)	Project Officer, Contracting Officer	Within 15 calendar days after each 12 month period from the time of contract award.
Transition Plan	3 1 (Original)	Project Officer, Contracting Officer	Prior to the contract completion date, as specified by the Project Officer
Final Report	3 1 (Original)	Project Officer, Contracting Officer	On or before the completion date of contract

The following Other Deliverables shall be submitted to the Project Officer only:

Item	Description	Due Date	Reference in SOW
Site Feasibility Assessment Visit Reports	Results and recommendations of site suitability	Within 10 working days from the last day of site visit.	A.3
Site Operational Assessment Visit Reports	Include an executive summary of findings, detailed findings and a list of corrective actions	Within 10 working days from the last day of site visit.	B.1.a.2)
Standardized Protocol and Associated Document Templates		Within 10 calendar days after request.	B.2.a.2)
Adjunctive Documents/Materials		Within 10 calendar days after request.	B.2.b.1)
Internal QA/QC - Progress of Remedial Action Report		Within 5 days after request.	B.5.c.
Internal QA/QC – Data Collection Reports	Report on verification, discrepancy and error rates of data collection, preparation and computer entry	Within 5 days after request.	B.5.h.
Training Materials	Training materials and all updates	Within 30 days after request.	B.6.c.
Monthly Training Schedules	Schedules for delivery of training	5 th day of each Month.	B.6.d.
Product/Agent Distribution Manual with SOPs	Compliance and management of product storage and distribution	Within 15 days prior to scheduled shipment.	B.9.d.
Initial Monitoring Plan	Monitoring plan for each trial with recommendations on the key variables and percentage of records to be monitored	Within 10 days prior to initial site visit.	C.3.a.
Site Monitoring Reports and Draft Letters to Principal Investigators		Within two (2) weeks from the last day of site visit.	C.4.a.
Serious Deficiencies Notice	Immediate notification of serious deficiencies/concerns regarding site performance	Telephone notification within 24 hours from the time of discovery.	C.4.b.
Monitoring Visit SOPs		Within 1 month after contract award.	C.8.
Safety Reports		Within 5 days of request.	D.3.
Adverse Event Review SOPs	Practices and procedures	Within 4 weeks after contract award.	D.4.
SAE Reports		Transmit immediately to DMID and DMID-designated entities.	D.9.
Pharmacovigilance/Safety Monitoring System Transition Plan		Within 3 months after contract award.	D.12.
Meeting Summary Reports		Within 72 hours after meeting	E.1.
Conference Call Minutes		Within 72 hours after conference call	E.2.

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

<http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm>

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: <http://www.arnet.gov/far/>.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR

<u>Clause No.</u>	<u>Date</u>	<u>Title</u>
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over \$100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over \$100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over \$100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over \$100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over \$100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Feb 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over \$100,000)

52.219-9	Jan 2002	Small Business Subcontracting Plan (Over \$500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (NOTE: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over \$100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over \$500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over \$100,000)

52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over \$100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over \$100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

<u>HHSAR Clause No.</u>	<u>Date</u>	<u>Title</u>
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.216-72	Oct 1990	Additional Cost Principles
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH
AND DEVELOPMENT CONTRACT – Rev. 07/2002]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following clause(s) will be made part of the resultant contract:

FAR 52.215-15, PENSION ADJUSTMENTS AND ASSET REVERSIONS (DECEMBER 1998), is deleted in its entirety.

ALTERNATE II (OCTOBER 2001) of FAR 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (JANUARY 2002) is added.

FAR 52.225-1, BUY AMERICAN ACT - SUPPLIES (MAY 2002) is deleted in its entirety and FAR 52.225-5, TRADE AGREEMENTS (FEBRUARY 2002) is substituted therefor.

FAR 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefor. **[Note: When this contract is fully funded, FAR 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR 52.232-20, LIMITATION OF COST will become applicable.]**

ALTERNATE I, (DECEMBER 1991), of FAR 52.233-1, DISPUTES (DECEMBER 1998) is added.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

FAR 52.215-17, Waiver of Facilities Capital Cost of Money (OCTOBER 1997).

FAR 52.227-14, Rights in Data - General (JUNE 1987)

Alternate III (JUNE 1987), FAR 52.227-14, Rights in Data--General (JUNE 1987).

Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(3) of the clause are expressly stated as follows:

FAR 52.227-16, Additional Data Requirements (JUNE 1987).

FAR 52.227-17, Rights in Data--Special Works (JUNE 1987).

FAR 52.227-19, Commercial Computer Software--Restricted Rights (JUNE 1987).

FAR 52.230-2, Cost Accounting Standards (APRIL 1998).

FAR 52.230-6, Administration of Cost Accounting Standards (NOVEMBER 1999).

FAR 52.242-3, Penalties for Unallowable Costs (OCTOBER 1995).

FAR 52.251-1, Government Supply Sources (APRIL 1984).

- b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:

HHSAR 352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities (APRIL 1984).

- c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (MAY 2002)

- (a) **Definitions.** As used in this clause--

Commercial item, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

- (b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

- (c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

- (i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$500,000 (\$1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).
- (iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).
- (iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
- (v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (JUN 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

- (2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

- (d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: November 29, 2002] (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

<http://www.niaid.nih.gov/contract/ref.htm>

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- Technical Proposal Cover Sheet
- Technical Proposal Cost Information
- [Project Objectives – NIH-1688-1](#)
- Summary of Related Activities
- Government Notice for Handling Proposals

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- NIH-2043, Proposal Summary and Data Record
- Small Business Subcontracting Plan Format *[if applicable]*
- Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours
- Offeror's Points of Contact

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts
- NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)
- Safety and Health, HHSAR Clause 352.223-70
- Privacy Act System of Records
- Report of Government Owned, Contractor Held Property
- Disclosure of Lobbying Activities, OMB Form LLL

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals. You are required to submit one original paper copy of your proposal along with the number of extra copies required below.

ELECTRONIC SUBMISSION: In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DMID-03-33
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Joshua J. LaVine/Michelle Scala Contract Specialists Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Joshua J. LaVine/Michelle Scala Contract Specialists Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 150 PAGES

[INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.].

ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF “PROPOSAL INTENT TO RESPOND SHEET”:

Upon receipt by the Contracting Officer of the “Proposal Intent Response Sheet”, offerors will be provided, via e-mail correspondence, specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached “Proposal Intent Response Sheet” by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs \$10/month or \$100/year. Please link to the following URL for information:

<https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE>

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
 2. Log-in Name: Will be provided by the Contract Specialist.
 3. Log-in Password: Will be provided by the Contract Specialist.
4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.
- You must have Explorer 3.1 or higher.
 - It is essential that you use antiviral software to scan all documents.
 - Click on "Sign On" and enter your log-in name and password.
 - Click on "Browse" to locate your saved files on your computer.
 - Click on "Upload Proposal" after you have located the correct file.
 - After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
 - If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
 - If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-03-33

RFP Title: DMID Clinical Trial Management

Please review the attached Request for Proposal. Furnish the information requested below and return this page by November 29, 2002. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

☐ DO INTEND TO SUBMIT A PROPOSAL

☐ DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____

Address (print): _____

Project Director's Name (print): _____

Title (print): _____

Signature/Date: _____

Telephone Number and E-mail Address (print clearly):

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____

Title: _____

E-Mail Address: _____

Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:

CMB, NIAID, NIH

Room 2230

6700-B Rockledge Drive, MSC 7612

Bethesda, MD 20892-7612

Attn: Joshua J. Lavine/Michelle Scala

RFP-NIH-NIAID-DMID-03-33

FAX# (301) 480-5253

Email : JLaVine@niaid.nih.gov and ms35n@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

<http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf>

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "writing", or "*written*" any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time*," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

- (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--
 - (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
 - (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
 - (3) It is the only proposal received.
- (B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.
- (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
- (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
- (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.
- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
- (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
- (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
- (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
- (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

- (e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

- (2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

“Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation.”

- (3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

- (f) *Contract award.* (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

- (2) The Government may reject any or all proposals if such action is in the Government's interest.

- (3) The Government may waive informalities and minor irregularities in proposals received.

- (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.
- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) The Government may disclose the following information in postaward debriefings to other offerors:
 - (i) The overall evaluated cost or price and technical rating of the successful offeror;
 - (ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
 - (iii) A summary of the rationale for award; and
 - (iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

- (f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

- (1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.
- (2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

d. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that ONE AWARD will be made from this solicitation and that the award(s) will be made on/about June 30, 2003.

It is anticipated that the award(s) from this solicitation will be a multiple-year, cost-reimbursement, completion type contract with a period of performance of five (5) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. ESTIMATE OF EFFORT

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 53 FTEs per annum (approximately 110,240 direct labor hours per annum). This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are [significantly more important than cost or price/approximately equal to cost or price/significantly less important than cost or price]. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

- (a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

- (b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

l. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

m. **AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."**

Copies of the "Federal ADP and Telecommunications Standards Index" can be purchased from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.

n. **USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS**

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) Contract Type and General Clauses

It is contemplated that a cost-reimbursement, completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

a. Project Objectives, NIH-1688-1

The Offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- **For an Institution of Higher Education: The form MUST be completed in its entirety.**
- **For OTHER than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.**

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, "INSTRUCTIONS:"

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS.) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) Evaluation of Proposals

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) Privacy Act (Treatment of Proposal Information)

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(10) Selection of Offerors

- a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-
 - (1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

- (2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding \$25,000 will be published in the Commerce Business Daily and FedBizOpps.

(11) Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment _ to this RFP is an example of such a plan.

- a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b) *The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.*
- c) *The offeror understands that:*
 - (1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
 - (2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
 - (3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

- (4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
 - (5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
 - (6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d) Each plan must contain the following:
- (1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
 - (2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 - (3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
 - (4) A description of the method used to develop the subcontracting goals.
 - (5) A description of the method used to identify potential sources for solicitation purposes.
 - (6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 - (7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
 - (8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
 - (9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$500,000 adopt a plan similar to the plan agreed upon by the offeror.
 - (10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.
 - (11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

(12) HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

(13) Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$500,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: <http://www.sba.gov/size>

The Department of Commerce website for the annual determination is:
<http://www.arnet.gov/References/sdbadjustments.htm>

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation is **not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime	10%	\$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	\$150,000

***NOTE:** FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(14) Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(15) Salary Rate Limitation in Fiscal Year 2002 **

Offerors are advised that pursuant to P.L. 107-116, no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 107-116 applies only to Fiscal Year 2002 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 107-116 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

Information regarding the FY-2002 rate can be found at: <http://www.opm.gov/oca/02tables/ex.pdf>

It should be noted that a similar public law may be enacted in Fiscal Year 2003, at which time that public law will be incorporated into any resultant contract(s).

(16) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

- (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
- (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- (g) Certify, in each application/proposal for funding to which the regulations applies, that:

- 1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
- 2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
- 3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and
- 4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

- (a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.**

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

- (i) public disclosure of significant financial interests;
 - (ii) monitoring of research by independent reviewers;
 - (iii) modification of the research plan;
 - (iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
 - (v) divestiture of significant financial interests; or
 - (vi) severance of relationships that create actual or potential conflicts of interests.
- (b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(17) Electronic and Information Technology Accessibility

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

1. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and
2. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at <http://www.section508.gov> .

(18) Prohibition on Contractor Involvement with Terrorist Activities

The Offeror/Contractor acknowledges that U. S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

(19) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
- b) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
- c) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
- d) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- e) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a) Statement of Work

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) Technical Evaluation

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) Additional Technical Proposal Information

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.
- e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(5) Information Technology Systems Security

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site: <http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html>

c. **BUSINESS PROPOSAL INSTRUCTIONS**

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Information Other than Cost or Pricing Data

- a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

- b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. Subcontracted Items

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over \$550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. Raw Materials

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. Purchased Parts

Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. Fringe Benefits

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. Indirect Costs

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. Special Equipment

If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. Travel

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. Other Costs

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: <http://rcb.nci.nih.gov/forms/cpi.htm>

(4) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

- (1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

- (i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
- (ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--
 - (A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
 - (B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
 - (C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.
- (2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.
- (b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:
 - (1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.
 - (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

- (b) (1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(5) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(6) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

- (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

- (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
- (2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
- (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) Royalties

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

c) Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

- (1) The solicitation number (or other procurement identification number).
- (2) The offeror's name and remittance address, as stated in the offer.
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
- (4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
- (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

d) Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) Incremental Funding

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

- (a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional

funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

- (b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

f) Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)

(This is applicable if you are a commercial organization.)

- (a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.
- (b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

- ☐ The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).
- ☐ The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(7) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a) Willingness to perform as a subcontractor for specific duties (list duties).
- b) What priority the work will be given and how it will relate to other work.
- c) The amount of time and facilities available to this project.
- d) Information on their cognizant field audit offices.
- e) How rights to publications and patents are to be handled.
- f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm>

(8) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(9) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(10) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

(11) Certification of Visa's for Non-U.S. Citizens

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its territories, then the offeror must indicate in the proposal that these individuals have the required visas.

d. **ADDITIONAL COST AND TECHNICAL PROPOSAL INSTRUCTIONS AND EVALUATION INFORMATION**

THE FOLLOWING INFORMATION IS SPECIFIC FOR PURPOSES OF RESPONDING TO THIS RFP. ALL OFFEROR(S) SHOULD PROVIDE SPECIFIC DOCUMENTATION IN THEIR PROPOSAL WITH REGARDS TO THESE ITEMS.

1. GENERAL COST PROPOSAL INFORMATION

Due to the nature of this contract, the workload (number and types of trials) is not known at this time. For cost estimating and planning purposes, Offerors should assume that the contract would support the following studies/activities:

- a. Clinical Trial preparation/operational assistance – Assume that annually the contractor will work with DMID clinical trial sites in the coordination of the following clinical trials:
 - 20 new Phase I single-site clinical studies with a sample size of 50 per study and a trial duration of 1 year
 - 5 new Phase II single-site clinical studies with a sample size of 100 per study and a trial duration of 1 year
 - 5 new Phase II multi-center trials involving 5 clinical sites with a sample size of 100 per site and a trial duration of 1 year.
 - 1 new Phase III multi-center trial involving 10 clinical sites with a sample size of 300 per site and a trial duration of 3 years.
 - Assume that operational assistance activities will be required for 25 additional study sites involved in the conduct of on-going clinical trials and studies.
- b. Conduct site feasibility assessment visits to 10 potential clinical sites (80% domestic and 20% international) per year. Assume that each site visit will last 2 days.
- c. Conduct site operational assessment visits to 60 clinical sites (80% domestic and 20% international) per year. Assume that each site will require an initial site visit lasting 2 days and a follow-up visit lasting 4 days.
- d. Protocol/Adjunctive Document Development – Assume that 20 new clinical studies requiring document development will be initiated annually. Assume 3 iterations per protocol document.
- e. Clinical studies are sponsored by DMID in Europe, Africa, South America and Asia. Plan on translating, including back translating, 5 consent forms a year.
- f. Assume that 20 training classes involving 15 participants/each will be conducted annually. Of which, 5 training classes will be conducted in Bethesda, Maryland (assume at an NIAID/DMID facility) and the remaining will be conducted at clinical sites within the U.S. For the training conducted in Bethesda, MD, travel costs for the participants should be included.
- g. Product shipment and associated costs – Assume that 25 shipments are to be made each year to both domestic and foreign sites, for a total of 50 shipments per year. Many of the shipments have strict cold chain requirements.
- h. Assume that 120 *external* QA site monitoring visits will be conducted annually. Two monitors will attend each visit and the visit duration will be for a period of 4 days. Assume that 80% of the monitoring visits will be to domestic sites and 20% will be to international sites.
- i. Assume the processing of 100 - 500 SAE reports per year collected from 130 clinical sties, with approximately 20% of the sites being international.
- j. Meeting Costs - Assume that 25 face-to-face meetings requiring the travel of 10 investigators/each from various domestic locations will be conducted annually. Assume that 500 teleconferences will be conducted annually.

- k. Assume annual subcontract costs of \$500,000 for the provision of routine or specialized immunogenicity tests (e.g., ELISA, ELISPOT, Antibody neutralization) and/or therapeutic-related (e.g., viral load, CD4) assessments.
- l. Experimental agents to be evaluated by DMID clinical trial sites will be provided at no cost to the Contractor. Therefore, Business Proposals shall not include any costs associated with the purchase of investigational agents.

2. UNIFORM ASSUMPTION:

Software and database systems, including source code information, developed or modified for use under this contract are subject to the following FAR clauses: 52.227-14, Rights in Data - General, 52-227-16, Additional Data Requirements, and 52-227-19, Commercial Computer Software- Restricted Rights.

Assume annual subcontract costs of \$500,000 for the provision of routine or specialized immunogenicity tests (e.g., ELISA, ELISPOT, Antibody neutralization) and/or therapeutic-related (e.g., viral load, CD4) assessments.

3. PERSONNEL

In responding to this RFP, the Offeror must describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract. In addition, the Offeror must describe an administrative framework indicating clear lines of authority.

Documentation must also be provided on the qualifications, knowledge, experience, education, competence, availability, and decision-making authority of the Principal Investigator, Project Directors/Managers, Technical Staff, and Administrative Support Staff. Offerors must provide information on the extent to which outside consultants will be used, as well as assurance of their availability, and the percentage of time each staff member (including proposed subcontractors and consultants) will contribute to the project. Resumes, endorsements, and explanations of previous efforts provided for the Principal Investigator, Project Directors/Managers, Technical Staff and the Administrative Support Staff must clearly demonstrate relevant knowledge, training, experience, and specific accomplishments. Documentation must include all previous and current projects of a similar nature, including, where applicable, the contract number or grant number, the sponsoring agency, the project officer, and the name and description of the project.

The Offeror's role in the support of each study will be defined by the Project Officer. Offerors must have the flexibility to adjust the relative time commitments of their staff to meet the varying needs of the studies to be undertaken.

4. SUBCONTRACTING

The Government is aware that no single organization or institution may have the expertise and facilities required to perform all requirements set forth in this statement of work. Therefore, it may be necessary for the Contractor to subcontract a portion of the work. If a subcontractor(s) is proposed, similar technical information must be provided by the subcontractor(s) as part of the Technical Proposal as that required by the Prime Contractor; i.e., technical approach, knowledge, methods, experience, personnel qualifications, specific responsibilities and work to be performed for contract facilities, resources, etc. Since the Government is seeking to support the best possible design and development teams, the primary Contractor is not limited to a domestic institution or organization. Cost details must also be provided for the subcontractors(s). The review and selection criteria for adding additional subcontractors during the contract performance must be clearly delineated. Additionally, the relationship between the subcontractor(s) and the Prime contractor in conducting the Statement of Work must be clearly delineated.

5. ON-SITE STAFF

Due to the nature of this requirement and the need for close interaction with DMID staff, some contractor staff will need to work on-site at DMID, NIAID. Although no geographical restrictions have been placed on this requirement, Offerors who are not located in the Washington, DC metropolitan area, or do not have satellite offices in the area must adequately address in their proposal how this need for a local presence will be satisfied.

6. TRIAL LOCALES

The majority of the clinical trials supported under this contract will be performed at domestic sites; however, some international trials will be supported by this contract. Potential international trial sites may include, but are not limited to the following geographical areas: Europe, Africa, South America and Asia. Providing clinical trials management support to these sites would require a set of policies, procedures and staff to operate in a culturally acceptable manner in these countries.

7. STANDARDIZED PROTOCOL AND ASSOCIATED DOCUMENT TEMPLATES

The Offeror's technical proposal must include samples of standardized protocol templates, including Case Report Forms, for a Phase I vaccine study and a Phase I drug study.

8. STANDARD OPERATING PROCEDURES

Technical proposals must include samples of standard operating procedures (SOPs) for the following:

- Study documents preparation and review;
- Quality Control and Quality Assurance (QC/QA) activities; and
- Receipt, follow-up, tracking, and disposition of SAE reports.

9. QUALITY ASSURANCE PLAN FOR MONITORING

Proposals must include a copy of the Offeror's Quality Assurance plan for monitoring practices along with a complete set of monitoring SOPs. DMID utilizes a standard monitoring report form. A copy of the form is available upon written request made to the Contracting Officer named in the solicitation.

10. COMMUNICATIONS MANAGEMENT

Technical information to guide decisions for communications management include the following:

- The NIAID wide area network (WAN) consists of servers, workstations, routers, cabling, telecommunications lines, operating systems and applications. This WAN connects several networks in the Washington, D.C., metropolitan area with the Rocky Mountain Labs in Montana.
- The NIAID servers are a mixture of single, dual, and quad-processor Pentium, Pentium II, Pentium III, and Pentium 4 high performance personal computers. They operate under Microsoft Windows NT 4.0 and Windows 2000 Advanced Server network operating system using an NT Domain model. TCP/IP (Transmission Control Protocol/Internet Protocol) and AFP (Apple File Protocol) are the network communications protocols employed for all connectivity to these servers.
- The PC workstations are Intel Pentium III and Pentium 4 (and a few Apple Macintosh) personal computers. The Intel based workstations run Windows 98 Second Edition along with some newer computers running Windows 2000 Professional and Windows XP Professional. All PC workstations typically use TCP/IP to communicate with server devices.
- Connectivity between the networks is facilitated by routers and telecommunications lines. The NIAID uses CISCO routers to connect the networks at different physical locations via a T1 (1.54mb/sec), and T3 (44.736 Mbps) circuits. 100 mb/sec fiber is also used between networks. The overall network is collapsed into a "backbone" CISCO router.
- The NIAID internal building cable plants are based on 100 mb/sec ethernet. NIAID employs ethernet hubs made by a variety of manufacturers including Enterasys to connect networked devices across 100baseT [(twisted pair telephone-type (category 5)], coaxial and fiber optic cabling.

- The NIAID has settled on several Windows applications as Institute standards. These include Microsoft Word for word processing, Microsoft Access for databases, Microsoft PowerPoint for presentations, and Microsoft Excel for spreadsheets. Microsoft Exchange is the Institute standard for electronic mail. To access electronic mail, the workstation clients Use Microsoft Outlook.
- NIAID supports email connectivity from its clients, contractors and from other government agencies via the Internet SMTP (Simple Mail Transport Protocol) email facility. Additionally, NIAID has a World Wide Web site at <http://www.niaid.nih.gov>

11. INFORMATION MANAGEMENT SYSTEMS

Offerors must describe in detail the various components of the proposed data systems and how they will function with respect to DMID and its clinical sites. Also, predicted upper limits for time duration of the steps needed to accomplish the data management activities described in the Statement of Work.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost/price, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation are also important to the overall contract award decision. Technical evaluation factors however are significantly more important than cost or price and SDB participation factors. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government based on the evaluation factors set forth in this Section.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

- (a) Extent of commitment to use SDB concerns
- (b) Complexity and variety of the work SDB concerns are to perform
- (c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

<u>CRITERIA</u>	<u>WEIGHT</u>
1. <u>Technical Approach</u>	40 points
<p>The technical adequacy and feasibility of the proposed technical approaches, including alternative strategies and identification of potential obstacles and solutions for such obstacles in the performance of all the requirements of the statement of work. This will include the following:</p> <ul style="list-style-type: none">a) Ability to provide clinical site preparation support services and clinical trial operational assistance to DMID clinical trial sites involved in the conduct of Phase I-IV trials in domestic and international settings. This includes the participation in review of site operations, protocol and adjunctive document development, establishment of internal quality control/quality assurance programs, and the provision of training;b) Performing External Quality Assurance (QA) Monitoring Activities;c) Establishment and maintenance of a global Adverse Event/Serious Adverse Event (AE/SAE) reporting system;d) Providing general and protocol-specific clinical research management of a global portfolio of DMID Phase I-IV clinical trials in domestic and international settings, including research program management support, meeting management and communications activities;e) Ability to meet the information management needs of the Statement of Work; andf) Ability to perform clinical site feasibility assessment activities.	
2. <u>Qualifications and Availability of Proposed Scientific and Management Staff</u>	30 points
<p>Adequacy and feasibility of the proposed staffing for the conduct of the project, including the appropriateness of the time commitments of the proposed positions, the clarity and appropriateness of assigned roles, responsibilities, lines of authority (provide an organizational chart which includes all personnel), plans for back-up staffing as the need arises, and the logistical adequacy of the proposed staffing plan. Offerors should provide appropriate and multi-disciplinary staff with relevant experience in a broad array of clinical research management associated with the planning, implementing and conduct of Phase I-IV clinical trials evaluating vaccines, other biologicals and drugs for infectious diseases, other than HIV, in domestic and international settings.</p> <ul style="list-style-type: none">a) Leadership and Management Structure<p>Proposed project management, technical and administrative leadership. This must include the documented training, experience, leadership, and availability of a lead Principal Investigator with domestic and international research program management experience and Investigational New Drug (IND) clinical trials expertise, and the expertise and experience of the team of Project/Site Managers and monitors. The administrative framework indicating clear lines of authority and responsibility for the overall DMID clinical research program management as well as protocol-specific management and its relationship to the sites and general program management must be described. The overall competence of the Principal Investigator and the</p>	

surrounding leadership to successfully manage a project of this size and complexity must also be defined. A doctoral level Principal Investigator is not required. Emphasis is placed on clinical trials management experience within the context of large research programs and international trials. Special attention will be placed on ability to separate operational units (site operations, QC/QA internal monitoring, and external QA monitoring) to eliminate potential conflicts of interest, and to ensure the external QA monitoring remains independent from other site management activities.

b) Technical Staff

Documented training, experience, capability and availability of the proposed research, technical, management, and support staff to perform the tasks outlined in the Statement of Work. Expertise in similar projects, with a special emphasis on their ability to anticipate the variety of special conditions likely to be encountered, especially among resource constrained sites, will also be evaluated, along with the technical staff's basic understanding of clinical research requirements and Good Clinical Practices. Technical staff must be able to undertake arduous travel within 14 days notice.

c) Subcontractors

Documented training, experience and availability of any proposed subcontractor(s), their documented capability to perform the proposed work, and expertise in similar projects. The logistical adequacy of the plan for use of the subcontractor(s) in the conduct of the project, including the time commitments of professional and technical staff. Quality and feasibility of the plan to identify the need to add, replace, or remove the subcontractor's technical staff, dependent on the progress or change in direction. Adequacy of plans for evaluating the performance of subcontractors.

3. Organizational Experience, Facilities and Resources

30 points

- a) Experience in managing large and complex clinical research programs.
- b) Capacity and capability to work with DMID-specified grantees, contractors and pharmaceutical partners, as well as possess the ability to establish the necessary linkages (administrative, logistic, operational, etc.) as required for sound clinical trial management.
- c) Documented availability and adequacy of facilities, equipment, and resources necessary to effectively carry out all phases of the proposed project.
- d) Ability to successfully contract with Contract Research Organizations, Site Management Organizations, Federal entities, Pharmaceutical companies, Non-Governmental Organizations, Non-U.S. organizations/companies.
- e) Suitability of proposed plans for start-up and for orderly transition to a successor Contractor.

TOTAL: 100 Points